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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,359	10/20/2003	Natarajan Ranganathan	KBI-0015	4537

7590 04/04/2007

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EXAMINER	
DAVIS, RUTH A	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,359	RANGANATHAN, NATARAJAN	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Request for Continued Examination filed on January 5, 2007 and the amendment and response filed on November 27, 2006 have been received and entered into the case. Claims 1 – 11 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 – 3 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Halpin-Dohnalek.

Applicant claims a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the water activity is less than about 0.47. The probiotic bacteria is selected from a list; the product provides 5 – 20 billion CFUs; the carbohydrate is selected from a list; and the composition further comprises at least one vitamin and mineral.

Halpin-Dohnalek teaches a powdered nutritional composition comprising protein, fat, carbohydrates and the probiotic bacteria *Lactobacillus reuteri, L. acidophilis* and *Bifidobacterium infantis* (abstract). The reference teaches that the composition is useful for maintaining GI health, and teaches a method for restoring GI health by administering the composition (abstract). The compositions further comprise minerals and vitamins (col.3 line 30-50) as well as sucrose (claims). Halpin-Dohnalek provides examples of the composition wherein the compositions provide $10x10^9 - 5x10^9$ (or 5 – 10 billion) CFUs of *L. reuteri* (example 1).

Halpin-Dohnalek does not teach the claimed amounts of each component or wherein the water content is less than about 0.47. However the reference does teach that the composition of their mixture may be varied (column 4, lines 1-28) and wherein the composition is a powder (abstract). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant argues that the reference only provides a single example with bacteria and sucrose and that there is no motivation to modify the composition to get to the claimed amounts.

However, these arguments fail to persuade because the reference clearly demonstrates that the bacteria are used in food compositions with the intention of maintaining and/or enhancing GI health. Regarding the amounts, the reference clearly suggests that modifying the amounts can be optimized according to use (col.4). Thus, at the time of the claimed invention,

one of ordinary skill in the art would be motivated to optimize the amounts of each ingredient with a reasonable expectation for successfully obtaining an effective food composition to maintain and/or enhance GI health.

3. Claims 1, 3 – 5, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul.

Applicant claims to a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the composition has a water activity of less than 0.47. The carbohydrate, fat, and protein are each selected from a list. The composition may further comprise at least one prebiotic selected from a list. Applicant finally claims a method for restoring and maintaining gastrointestinal (GI) health, comprising administering to a subject at least one food or nutritional product comprising an effective amount of probiotic bacteria and an effective amount of a prebiotic; and a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an ammoniaphilic urea-degrading microorganism with pH stability and urea degrading activity.

Paul teaches compositions for restoring and maintaining GI health, comprising immunogloblins (protein), FOS (prebiotic), pectin (prebiotic), *Lactobacillus* and *Bifidobacteria* (abstract), wherein the compositions are powdered (col.13-14). The immunoglobulin, or protein, is derived from milk or whey (abstract); and the bacteria may be *Lactobacillus acidophilis, L. bulgaricus, L. casei, L. fermentum, L. salivaroes, L. brevis,* or *L. plantarum,* or *Bifidobacterium*

adolescentis, B. infantis, B. longum, B. thermophilis, or *B. bifidum* (col.4 line 20-29). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45).

Although Paul does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics.

Paul does not teach the claimed amounts of each component or wherein the water content is less than about 0.47. However, Paul teaches that the composition of the mixture may be varied (column 4, lines 1-52; and column 13, line 47, through column 14, line 38). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant argues that the reference does not provide a motivation to optimized amounts of the ingredients, that the ingredients are not recognized as result effective variables, that the bacteria is optional and is therefore not optimizable, and that the reference teaches powders and liquids.

However, these arguments fail to persuade because the reference clearly teaches the amounts of ingredients are optimized depending on the individual and desired effect (i.e. to maintain or treat a condition of the GI tract) (col.4, 14). Thus, the reference clearly suggests to one in the art that the ingredients are result effective and that the amounts can be optimized as such. Moreover, the reference clearly motivates one in the art to combine the instant ingredients together in varying amounts to achieve the claimed effects of maintaining and/or enhancing GI health. Further, as the reference teaches the compositions in powder and liquid forms, it is clear that the amount of water (or water activity) can be optimized by one in the art.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo.

Applicant claims a yogurt or yogurt based product for maintaining or enhancing GI health, comprising at least one probiotic, carbohydrate and protein, wherein the probiotic is present at 5 – 20 billion CFUs.

Costanzo teaches a yogurt composition (abstract) comprising *Lactobacillus bulgaricus* (probiotic), whole milk (milk proteins), and dextrose (carbohydrate) and soy lecithing (fat) (examples 1 and 2, claims).

Costanzo does not teach the claimed amounts of bacteria. However, Costanzo teaches that the composition of the mixture may be varied (column 6, lines 50-59, and column 7, lines 20-32), and that the compositions are intended to keep milk ferments (or bacteria) in high number (col.1 line 12-17) such as 10^6 (col.11-12). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of

components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant argues that the reference does not teach the claimed amounts of bacteria or the therapeutic function; and that there is no motivation to optimize the number of bacteria. Applicant additionally argues that the instant composition is better due to the combination of fat and probiotic.

However, these arguments fail to persuade because it is noted that the claimed yogurt contains high numbers of CFUs, specifically 10^6. While this is not the amount claimed, it is high amounts of bacteria which are known to maintain and enhance GI health (as evidenced by Halpin-Dohnnalek and Paul). Thus, it would have been well within the purview of one in the art to optimize the amounts of bacteria as a matter of routine experimentation. Finally, regarding applicant's assertions that the combination of fat and probiotic, it is noted that the rejected claim does not require fat thus the argument is not commensurate in scope with the rejected claim.

5. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halpin-Dohnalek and Paul.

Applicant claims to a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of

one protein ingredient, wherein the composition has a water activity of less than 0.47. The probiotic bacteria, carbohydrate, fat, and protein are each selected from a list; the product provides 5 – 20 billion CFUs; the carbohydrate is selected from a list; and the composition further comprises at least one vitamin and mineral. Applicant additionally claims a food product comprising carbohydrates, 2 – 12% fat, protein, vitamin, mineral, probiotic and probiotic wherein the composition has a water activity of less than about 0.47. Applicant finally claims a method for restoring and maintaining gastrointestinal (GI) health, comprising administering to a subject at least one food or nutritional product comprising an effective amount of probiotic bacteria and an effective amount of a prebiotic; and a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an ammoniaphilic urea-degrading microorganism with pH stability and urea degrading activity.

Halpin-Dohnalek teaches a powdered nutritional composition comprising protein, fat, carbohydrates and the probiotic bacteria *Lactobacillus reuteri, L. acidophilis* and *Bifidobacterium infantis* (abstract). The reference teaches that the composition is useful for maintaining GI health, and teaches a method for restoring GI health by administering the composition (abstract). The compositions further comprise minerals and vitamins (col.3 line 30-50) as well as sucrose (claims). Halpin-Dohnalek provides examples of the composition wherein the compositions provide $10x10^9 – 5x10^9$ (or 5 – 10 billion) CFUs of *L. reuteri* (example 1).

Paul teaches compositions for restoring and maintaining GI health, comprising immunogloblins (protein), FOS (prebiotic), pectin (prebiotic), *Lactobacillus* and *Bifidobacteria* (abstract), wherein the compositions are powdered (col.13-14). The immunoglobulin, or protein,

is derived from milk or whey (abstract); and the bacteria may be *Lactobacillus acidophilis, L. bulgaricus, L. casei, L. fermentum, L. salivaroes, L. brevis,* or *L. plantarum,* or *Bifidobacterium adolescentis, B. infantis, B. longum, B. thermophilis,* or *B. bifidum* (col.4 line 20-29). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45). Although Paul does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics.

The references do not teach the all of the ingredients together in a single composition in the claimed amounts, with the claimed water activity. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Furthermore, the references teach that the composition of their mixture may be varied (Halpin-Dohnalek, column 4, lines 1-28; Paul, column 4, lines 1-52; and column 13, line 47, through column 14, line 38) and wherein the composition is a powder (Halpin-Dohnalek, abstract). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition.

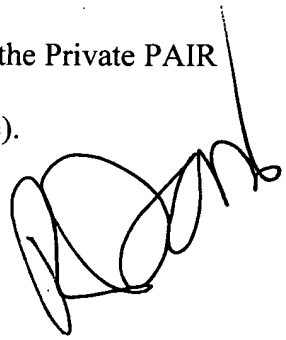
This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth A. Davis
Primary Examiner
Art Unit 1651

March 29, 2007